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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/836,278	04/18/2001	David Mack	03848.00065	5471

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EXAMINER	
GOLDBERG, JEANINE ANNE	
ART UNIT	PAPER NUMBER
1634	

DATE MAILED: 02/27/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	09/836,278	MACK, DAVID	
	Examiner	Art Unit	
	Jeanine A Goldberg	1634	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *three* MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *December 4, 2002* .

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *11-17, 29-38, 1-43* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *11-17, 29-38, 1-43* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

11)☐ The proposed drawing correction filed on _____ is: a)☐ approved b)☐ disapproved by the Examiner.

If approved, corrected drawings are required in reply to this Office action.

12)☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

13)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____ .

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

14)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).

a) ☐ The translation of the foreign language provisional application has been received.

15)☒ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s) *0401* .
4) ☐ Interview Summary (PTO-413) Paper No(s). _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: .

DETAILED ACTION

1. This action is in response to the papers filed December 4, 2002. Currently, claims 11-17, 29-32, 34-37 are pending.

2. All arguments have been thoroughly reviewed but are deemed non-persuasive for the reasons which follow.

3. Any objections and rejections not reiterated below are hereby withdrawn in view of the amendments to the claims and applicant's arguments.

4. This action contains new grounds of rejection.

Priority

5. This application claims priority to 09/086,285, filed May 29, 1998 which is a CIP of US 98/01206, filed January 12, 1998 which claim priority to provisional application 60/035,327, January 13, 1997.

Specification

6. The disclosure is objected to because it contains an embedded hyperlink and/or other form of browser-executable code. Applicant is required to delete the embedded hyperlink and/or other form of browser-executable code. See MPEP § 608.01.

It is noted that page 43, contains a hyperlink, for example.

Double Patenting

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent

and to prevent possible harassment by multiple assignees. See *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970);and, *In re Thorington,* 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent is shown to be commonly owned with this application. See 37 CFR 1.130(b).

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

7. Claims 11-17, 29-32, 34-37 are rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over Claims 1-7 of U.S. Patent No. 6,303,301.

An obviousness-type double patenting rejection is appropriate where the conflicting claims are not identical, but an examined application claim is not patentably distinct from the reference claim(s) because the examined claim is either anticipated by or would have been obvious over, the reference claim(s). See e.g., *In re Berg*, 140 F.3d 1428, 46 USPQ2d 1226 (fed. Cir. 1998); *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985).

Here, Claims 1-7 of U.S. Patent No. 6,303,301 recites a method of a functional mutation in a target upstream regulatory gene, specifically in p53 by making a reference sample having a wild type up-stream regulatory gene, i.e. p53 and a target sample from cells suspected of having a mutation in this gene, detecting the expression of more than 100 down-stream genes in the reference and the target and comparing to detect the functional mutations or inactivation of the gene. The claims of patent 6,303,301 are drawn to the same method except it is further limited only to p53, using downstream

genes, gadd45, cyclin G, p21, Bax, IGF-BP3 thrombospondin and c-myc and wherein loss of function is detected if expression in up-regulated genes is 5 times less in target cells or expression of down regulated genes is at least 5 times more in target cells. The method of Claim 1-7 differs from Claim 11-17, 29-32, 34-37 herein in that it fails to disclose detecting of more than 100 down-stream genes. However, the portion of U.S. Patent No. 6,303,301 that supports detecting of at least 100 genes is located in col. 6, lines 15-20; col. 8, lines 60. Therefore, it would have been obvious to modify the method of Claim 1-7 of U.S. Patent No. 6,303,301 such that at least 100 genes were analyzed to enable studying normal and abnormal functions of specific genes and to compare regulatory relationships among genes with statistical confidence. One having ordinary skill in the art would have been motivated to make such a modification to optimize.

Response to Arguments

The response traverses the rejection. The response asserts that a terminal disclaimer will be filed when necessary. Thus for the reasons above and those already of record, the rejection is maintained.

8. Claims 11-17 are rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over Claim 1-7 of U.S. Patent No. 6,177,248.

It is noted that the instant application is not assigned with the PTO. It is also noted that the parent application is assigned to Affymetrix, Inc. Therefore, since the

application is a continuation of US Pat. 6,303,301, it is presumed that the instant application is also assigned to Affymetrix. In the event that there is such a common assignment exists, the following rejection is appropriate.

An obviousness-type double patenting rejection is appropriate where the conflicting claims are not identical, but an examined application claim is not patentably distinct from the reference claim(s) because the examined claim is either anticipated by or would have been obvious over, the reference claim(s). See e.g., *In re Berg*, 140 F.3d 1428, 46 USPQ2d 1226 (fed. Cir. 1998); *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985).

Here, Claims 1-7 of U.S. Patent No. 6,177,248 recites a method of detecting a WT1 gene functional mutation in target cells by detecting expression of at least one down-stream gene of WT1 in a sample of a target cells and reference cells having a wild-type WT1 gene, comparing the expression of the down-stream genes in the target cells and the reference cells wherein a difference in the expression between the target cells and a reference cell suggests a WT1 functional mutation in the target cells. The method of Claims 1-7 differs from Claim 11-17 herein in that it fails to disclose detecting the expression of more than 100 down-stream genes. However, the portion of U.S. Patent No. 6,177,248 that supports detecting of more than 100 down-stream genes teaches 7,00 genes were monitored. Therefore, it would have been obvious to modify the method of Claim 1-7 of U.S. Patent No. 6,177,248 such that the more than 100 genes are monitored to study the expression patterns. One having ordinary skill in the

art would have been motivated to make such a modification to optimize the analysis of down-stream genes.

9. Claims 11-17 are rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over Claim 1-7 of U.S. Patent No. 6,258,536.

It is noted that the instant application is not assigned with the PTO. It is also noted that the parent application is assigned to Affymetrix, Inc. Therefore, since the application is a continuation of US Pat. 6,303,301, it is presumed that the instant application is also assigned to Affymetrix. In the event that there is such a common assignment exists, the following rejection is appropriate.

An obviousness-type double patenting rejection is appropriate where the conflicting claims are not identical, but an examined application claim is not patentably distinct from the reference claim(s) because the examined claim is either anticipated by or would have been obvious over, the reference claim(s). See e.g., *In re Berg*, 140 F.3d 1428, 46 USPQ2d 1226 (fed. Cir. 1998); *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985).

Here, Claims 1-7 of U.S. Patent No. 6,258,536 recites a method of detecting a BRAC1 gene functional mutation in target cells by detecting expression of a plurality of down-stream gene of BRAC1 in a sample of a target cells and reference cells having a wild-type BRAC1 gene, comparing the expression of the down-stream genes in the target cells and the reference cells wherein a difference in the expression between the

target cells and a reference cell suggests a BRAC1 functional mutation in the target cells.

The method of Claims 1-7 differs from Claim 11-17 herein in that it fails to disclose detecting the expression of more than 100 down-stream genes. However, the portion of U.S. Patent No. 6,258,536 that supports detecting of more than 100 down-stream gene is found col. 15, lines 20-23. Therefore, it would have been obvious to modify the method of Claim 1-7 of U.S. Patent No. 6,258,536 such that the more than 100 genes are monitored to study the expression patterns. One having ordinary skill in the art would have been motivated to make such a modification to optimize the analysis of down-stream genes.

10. Claim11-17 are directed to an invention not patentably distinct from Claim 1-7 of U.S. Patent No. 6,258,536 or Claim 1-7 of U.S. Patent No. 6,177,248.

It is noted that the instant application is not assigned with the PTO. It is also noted that the parent application, now patent 6,303,301 is assigned to Affymetrix, Inc. Therefore, since the application is a continuation of US Pat. 6,303,301, it is presumed that the instant application is also assigned to Affymetrix. In the event that such a common assignment exists, the following rejection is appropriate.

Claims 11-17 of the instant application are generic to any target up-stream regulatory gene.

As provided in MPEP 700, Chart II-B, Assignee is required to Either: (a) name first inventor of conflicting subject matter under 102(f) or (g) or (b) show inventions were commonly owned at time of Applicant's invention.

Conclusion

11. **No claims allowable.** The prior art does not appear to teach at least 100 down-stream genes which are up or down regulated by said wild-type up-stream regulatory gene.

12. The prior art made of record and not relied upon is considered pertinent to applicant's disclosure.

A) Levine et al. (US Pat. 6,020,135, February 2000) teaches many genes which are induced and repressed by p53 status.

13. Any inquiry concerning this communication or earlier communications from the examiner should be directed to examiner Jeanine Goldberg whose telephone number is (703) 306-5817. The examiner can normally be reached Monday-Friday from 8:00 a.m. to 5:30 p.m.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Gary Jones, can be reached on (703) 308-1152. The fax number for this Group is (703) 305- 3014.

Any inquiry of a general nature should be directed to the Group receptionist whose telephone number is (703) 308-0196.

J. Goldberg

Jeanine Goldberg
February 21, 2003

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